Issue Snapshot on Deeming: Regulating Additional Tobacco Products

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), signed by the President in 2009, created the FDA Center for Tobacco Products and gave FDA powerful tools to protect the public's health through our oversight of the manufacture, distribution, and marketing of tobacco products. Under the law, FDA currently regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products. The law also gave FDA the ability to regulate additional tobacco products, commonly referred to as "deeming" them through rulemaking. The proposed rule would include the following products under FDA's authority: electronic cigarettes (e-cigarettes), cigars, pipe tobacco, waterpipe (hookah) tobacco, and novel products like nicotine gels and dissolvables not already under FDA's authority. FDA's proposed rule also would include tobacco product components or parts that are used in the consumption of a tobacco product, like e-cigarette cartridges. It would not include tobacco product accessories, like cigar cases.

WHY THE DEEMING PROPOSED RULE IS SO IMPORTANT FOR PUBLIC HEALTH

The 50th Anniversary Surgeon General's Report on Smoking and Health states that the annual death toll of smoking-attributable disease has risen to at least 480,000, up from an estimated 443,000 deaths in 2012. At today's rate of tobacco use, there will be more than 17 million avoidable deaths between now and mid-century. Additionally, youth use of certain unregulated tobacco products, such as e-cigarettes and cigars, is on the rise. FDA oversight of tobacco products can provide important information about proposed deemed tobacco products and help limit youth exposure to these products. The proposed rule would also enable FDA to explore whether different products pose different levels of risk and help the Agency develop policies to improve public health.

HIGHLIGHTS OF THE DEEMING PROPOSED RULE

Consistent with currently regulated tobacco products, under the proposed rule, makers of newly deemed tobacco products would, among other requirements:

- Register with FDA and report product and ingredient listings
- Only market new tobacco products after FDA review
- Only make claims of reduced risk if FDA confirms that scientific evidence supports the claim and that marketing the product will benefit public health as a whole
- Not distribute free samples

In addition, under the proposed rule, the following items would apply to newly deemed covered tobacco products:

- Minimum age and identification restrictions to prevent sales to underage youth
- Requirements to include health warnings
- Prohibition of vending machine sales, unless in a facility that never admits youth

The term "covered tobacco products" is defined here as those products deemed to be subject to the Food, Drug & Cosmetic Act under section 1100.2 of title 21 of the Code of Federal Regulations (CFR), other than a component or part that does not contain tobacco or nicotine.

PROPOSED RULE COMMENT OPPORTUNITIES

FDA welcomes and encourages comment on the proposed rule from the public. FDA will consider all comments and information submitted to the docket. The agency is specifically requesting comments on certain topics, including the following issues:

- FDA is seeking comment on the two options proposed for the categories of cigars that would be covered by this rule—specifically, whether all cigars should be subject to deeming and what provisions of the proposed rule may be appropriate or not appropriate for different kinds of cigars.
- FDA is aware that some tobacco products, such as e-cigarettes and cigars, are being marketed with characterizing flavors that may be attractive to youth. FDA is seeking research regarding the long-term effects of flavored tobacco product usage, including data as to the likelihood of flavored tobacco product use leading to cigarette use instead of or in conjunction with other tobacco products.
- FDA is seeking comment as to how noncombustible products (such as e-cigarettes) should be regulated. Particularly, FDA requests comments on behavioral data related to co-use of e-cigarettes and more traditional tobacco products, including data on the effects of e-cigarettes on the initiation and continuation of use of other tobacco products.
- FDA is seeking comment on the proposed addictiveness warning ("WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.") and any potential for consumer confusion, the proposed size of the health warnings that would be required by this rule, and the role that the size of such warnings has in helping to convey consumer information.
- FDA is proposing to extend the compliance period for submitting a marketing application under the substantial equivalence pathway to 24 months following the effective date of a final rule. FDA is also proposing a 24-month compliance period for the submission of premarket tobacco applications (PMTAs). FDA is specifically seeking comment on whether and, if so, how FDA should consider a different regulatory mechanism for newer proposed deemed tobacco products that cannot, as a practical matter, use the substantial equivalence pathway.
- FDA recognizes that some of the proposals in this document might impose significant costs on certain manufacturers, including the requirement to register and list products and the requirement for certain cigar manufacturers to randomly distribute and rotate warning statements on packages and advertisements, respectively. FDA seeks comment and data on alternative approaches for manufacturers to satisfy these requirements that would reduce costs for manufacturers yet would still be appropriate for the protection of public health.

To submit a comment, visit our comment opportunities page at: **www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm198169.htm**

Contact Us 1-877-CTP-1373 • AskCTP@fda.hhs.gov • www.fda.gov/tobacco
FDA Center for Tobacco Products • 9200 Corporate Blvd. • Rockville, MD 20850-3229

Last Updated May 2014
CTP-32